K072516 | 51
p1/5

SECTION 9: 510(K) SUMMARY

1. Summary Preparation Date: June 12, 2007

2. 510(k) Applicant Information:

OCT 18 2007

Name: Midmark Diagnostics Group
Address:
3300 Fujita Street
Torrance, CA 90505
USA
FDA Establishment registration Number: 2081230
Contact Name: Tony Capparelli, Director of Product Development
Phone Number: 310-257-7217
Fax Number: 310-530-1421

3. Device Names and Designations

Proprietary Name: IQmark® Vital Signs Monitor
Module Configuration:

NIBP*	Temp	SpO_2
X	X	X

* Noninvasive Blood Pressure

Overall Device Common/Usual Name: Vital Signs Monitor
Overall Device Classification Name: Monitor, Physiological, Patient (Without Arrhythmia Detection)

Product Codes, Regulations, Class, and Panels:

Component	Product Code	Regulation Number	Class	Regulation Medical Specialty	Review Panel
Overall Device	MWI	870.2300	2	Cardiovascular	Cardiovascular
NIBP	DXN	870.1130	2	Cardiovascular	Cardiovascular
Oximeter	DQA	870.2700	2	Cardiovascular	Anesthesiology
Thermometer	FLL	880.2910	2	Gen. Hospital	Gen. Hospital

4. Substantial Equivalency: The Midmark Diagnostics IQmark® Vital Signs Monitor is substantially equivalent to these predicate devices:

- CAS Medical 740 Series Vital Signs Monitor (K033048)
- Welch Allyn Vital Signs Monitor (K053027)
- and IVAC Model 2080 Electronic Thermometer (K860436)

Like the CAS Medical 740 Series Vital Signs Monitor, the IQmark® Vital Signs Monitor is for monitoring of noninvasive blood pressure, oxygen saturation, pulse rate and temperature of adult, pediatric, and neonatal populations under care of health care professionals in general medical locations, hospitals, and alternative care environments.

The following tables compare the physical and performance characteristics of the proposed device to the predicate devices. Table 1 compares the IQmark® VSM to the CAS Medical 740 Series Vital Signs Monitor (K033048). Table 2 compares the IQmark VSM temperature module to the IVAC Model 2080 Electronic Thermometer (K860436) and Welch Allyn VSM 300 (K053027).

Table 1: Physical and Performance Characteristics of IQmark® Vital Signs Monitor To CAS Medical 740 Series Vital Signs Monitor

Characteristic	CAS Medical 740 Series Vital Signs Monitor (K033048)	IQmark® Vital Signs Monitor
Available module configurations	NIBP/Oximeter/Temperature	NIBP/Oximeter/Temperature
Overall operational modes	Adult, neonatal, power-on self-test, auto off, off and history	Adult, neonatal, power-on self test, automatic power down, and power down
NIBP modes	Manual, automatic, and stat	Manual, automatic, and stat
NIBP module operating principle	Oscillometric method employing a stepwise pressure deflation technique	Oscillometric method employing a stepwise pressure deflation technique
NIBP reading ranges	adult – systolic: 30-255 diastolic: 15-220 MAP: 20-235 neo – systolic: 30-135 diastolic: 15-110 MAP: 20-125	adult – systolic: 30-255 diastolic: 15-220 MAP: 20-235 neo – systolic: 30-135 diastolic: 15-110 MAP: 20-125
NIBP accuracy	+/- 5 mmHg, standard deviation no greater than 8 mmHg	+/- 5 mmHg, standard deviation no greater than 8 mmHg
NIBP cuff types	reusable and disposable	reusable and disposable
NIBP cuff sizes	adult, infant, and neonatal	adult, infant, and neonatal
SpO2 modes	Continuous monitoring and off	Continuous monitoring and off
SpO2 reading range (%)	0 - 100	0 - 100
SpO2 accuracy	adult: 70-100%: ± 2 counts neonate: 70-100%: ± 3 counts	adult: 70-100%: ± 2 counts neonate: 70-100%: ± 3 counts
SpO2 sensor types	Reusable and disposable	Reusable and disposable
SpO2 sensor sizes	adult, infant, and neonatal	Adult, infant, and neonatal
Alarm conditions	high and low alarms: pulse rate, systolic & diastolic BP, MAP, & SpO_2	high and low alarms: pulse rate, systolic & diastolic BP, MAP, & SpO_2
Power supply type	100-240 VAC (50-60 Hz) or charged NiMH battery	100-240 VAC (50-60 Hz) or charged sealed lead acid battery

Table 2: Physical and Performance Characteristics of IQmark® Vital Signs Monitor To IVAC Model 2080 Electronic Thermometer and Welch Allyn VSM 300

Characteristic	IVAC Model 2080 Electronic Thermometer (K860436)	Welch Allyn Vital Signs Monitor (K053027)	IQmark® Vital Signs Monitor
Thermometer type	Electronic, thermistor	Electronic, thermistor	Electronic, thermistor
Temperature reading range Continuous mode: Predictive mode:	 26.7 - 42.2 °C (80 – 108.0 °F) 31.6 – 42.2°C (88.9 – 108.0°F)	 28.9 – 42.2 °C (84.0 – 108.0 °F) Not specified	 28.9 – 42.2 °C (84.0 – 108.0 °F) 35.0 – 41.1 °C (95.0 –106.0 °F)
Accuracy Continuous mode: Predictive mode:	± 0.1 °C (± 0.2 °F) meet or exceeds ASTM E1112–00 requirements ±0.6 °C (+1.0 °F)	± 0.1 °C (± 0.2 °F) meet or exceeds ASTM E1112–00 requirements Not specified	± 0.1 °C (± 0.2 °F) meet or exceeds ASTM E1112–00 requirements ±0.6 °C (+1.0 °F)

The physical and performance characteristics of the IQmark® Vital Signs Monitor are very similar to those of the predicate device with a few non-significant differences in technological characteristics. The results of extensive software and hardware verification and validation testing, safety, and performance testing demonstrate that the different technological characteristics used in the IQmark® Vital Signs Monitor pose no new issues of safety and effectiveness and therefore is substantially equivalent to the predicate devices.

5. Performance Testing Summary:
The IQmark VSM has been tested for safety and efficacy and found to be in conformance with the following safety standards and performance standards applicable to blood pressure, SpO_2, and temperature modules:

EN 60601-1-2
IEC 60601-1-4
EN 60601-1-8
EN 9919
IEC 60601-1
ANSI/AAMI SP10
ASTM E1112

Additionally, the operational and performance specifications for each measurement module and for the IQmark Vital Signs Monitor as a system has been successfully verified and validated. Results demonstrate that the IQmark® Vital Signs Monitor poses no new issues of safety and effectiveness and therefore is substantially equivalent to the predicate devices.

The IQmark® Vital Signs Monitor Risk Analysis document identifies potential failure / hazard combinations associated with the use of the VSM, and mitigations to reduce patient risks. The document con-

cludes that the IQmark® Vital Signs Monitor is a safe device that poses no unacceptable risks to the patient.

6. Intended Use, Indications for Use, & Environment:

Intended Use and Indications: The Midmark Diagnostics IQmark® Vital Signs Monitor is intended to be used by clinicians and medically qualified personnel for monitoring adult, pediatric and neonatal patients for noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and body temperature. In adults and pediatric patients, temperature is monitored orally, rectally, or at axillary sites. In neonates (to 1 month) temperature is monitored at axillary sites only.

Intended Environment: The most likely locations for patients to be monitored are general medical locations, hospitals, and alternative care environments.

Contraindications: The IQmark® Vital Signs Monitor may not be suitable for use on patients under the following conditions:

a. Oral and Rectal temperature measurements are contraindicated for neonatal use.
b. Reusable SpO_2 sensors are contraindicated for prolonged use. The sensors must be removed every 4 hours and, if indicated by circulatory condition and skin integrity, reapplied to a different monitoring site.
c. Disposable SpO_2 sensors are contraindicated for patients that exhibit allergic reactions to adhesive tape. The sensors must be removed every 8 hours and, if indicated by circulatory condition and skin integrity, reapplied to a different monitoring site.

Complications: Except for temperature measurement, the IQmark® Vital Signs Monitor is a noninvasive device. The device is safe in construction and performance. This has been confirmed by the successful completion of Verification and Validation Testing, Biocompatibility Confirmation, and Risk Analysis.

Following are some possible complications:

a. Prolonged use of the adhesive tape used to attached disposable SpO_2 sensors may cause allergic reactions in some patients.
b. Prolonged use of reusable or disposable SpO_2 sensors may cut-off circulation in some patients.
c. Repeated application and use of temperature probe covers to the same tissue area may cause mild irritation at tissue site.
d. Failure to follow directions for rectal probe insertion could result in bowel perforation, especially in young children.

7. General Device Description: The Midmark Diagnostics IQmark® Vital Signs Monitor consists of the following three individual measurement Modules:

a. Noninvasive blood pressure (NIBP)
b. Pulse Oximeter
c. Temperature

In the Automatic or STAT Modes of operation, the NIBP Module automatically inflates an occluding cuff placed around the patient's arm or leg. It uses the oscillometric measurement technique to measure and record the patient's systolic and diastolic pressure as well as pulse rate. From these measurements the IQmark VSM also calculates the mean arterial blood pressure (MAP). Measurement results along with

operator prompts and error messages are indicated on the front panel display. The frequency of NIBP determination can be selected by the operator at fixed times between one and ninety minutes. The Manual Mode of operation also covers a variety of clinical uses. A variety of reusable and disposable cuff types and sizes is available for adult, pediatric, and neonatal applications. The NIBP Module requires routine calibration and maintenance.

The Pulse Oximeter Module measures and records the patient's arterial oxyhemoglobin saturation by measuring the absorption of red and infrared light passing through tissue (SpO_2). Changes in absorption caused by pulsations of blood in the patient's vascular bed are used to determine arterial oxygen saturation and pulse rate. Oxygen saturation and heart rate are indicated on the front panel display. A bar graph display gives the user a pulse-by-pulse visual indication of waveform signal quality. An audible indicator can be enabled which automatically generates a sound each time the SpO_2 sensor detects a pulse. The IQmark VSM utilizes the Masimo Set® oximeter. A variety of reusable and disposable sensor types and sizes is available for adult, pediatric and neonatal applications. These oximeter does not require routine calibration or maintenance.

The Temperature Module measures and records a patient's temperature in either the Predictive or Continuous Mode of operation using either oral (also used for axillary) or rectal probes. In the Predictive Mode, the thermometer's software predicts body temperature in about 15 seconds for oral and axillary temperatures. The IQmark VSM Temperature Module does not support Predictive Mode measurements for the rectal temperature probe. The default mode used by the IQmark VSM for oral temperature determinations is the Predictive Mode. The Continuous Mode is usually used for longer-term monitoring or when difficult situations prevent accurate patient temperature measurement in the Predictive Mode. Temperature probe covers are required and are available for the oral/axillary and rectal probes. The Temperature Module requires routine calibration and maintenance.

When the Alarm Setting Mode is activated, high and low alarm limits can be set (within specification and safety limits) for heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and SpO_2.

*8. **Device Materials Biocompatibility***: All blood pressure cuff, SpO_2 sensor, and temperature probe cover materials that come into contact with the patient's body tissue are in full compliance with all the applicable FDA biocompatibility requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2007

Midmark Diagnostics Group
c/o Mr. Tony Capparelli
Director of Product Development
3300 Fujita Street
Torrance, CA 90505

Re: K072516
Iqmark® Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: October 3, 2007
Received: October 4, 2007

Dear Mr. Capparelli:

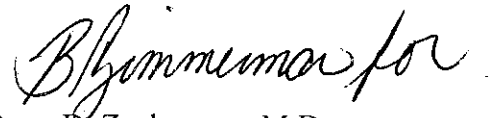
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072516/S1

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Midmark Diagnostics IQmark® Vital Signs Monitor

Indications For Use:

The Midmark Diagnostics IQmark® Vital Signs Monitor is intended to be used by clinicians and medically qualified personnel for monitoring adult, pediatric and neonatal patients for noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and body temperature. In adults and pediatric patients, temperature is monitored orally, rectally, or at axillary sites. In neonates (to 1 month) temperature is monitored at axillary sites only.

The most likely locations for patients to be monitored are general medical locations, hospitals, and alternative care environments.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Per 21 CFR 801.109 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072516